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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,663	03/05/2002	Helmut Eckert	900-9638D	8183

7590 09/23/2004

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/090,663		ECKERT ET AL.	
	Examiner		Art Unit	
	Alana M. Harris, Ph.D.		1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-28 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 and 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13-19, 23 and 28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/24/03; 06/01/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 13-28 are pending.

Claims 20-22 and 24-27, drawn to non-elected inventions, are withdrawn from examination.

Claims 13 and 15 have been amended.

Claims 13-19, 23 and 28 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. The information disclosure statement filed November 29, 2002 continues to fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because sheet 6 contains document listings that do not have publication dates and one of skill in the art would not be able to retrieve these articles based on the limited information provided. Furthermore, the parent application, as well as the continuing applications were not available to the Examiner at the time of examination. Accordingly, not all documents noted on the eight sheets of the IDS filed November 29, 2002 were not considered and will review these documents when they are accessible.

Oath/Declaration

4. Applicants have submitted an application data sheet on July 16, 2004, which lists the proper United Kingdom application number **9210944.6**, filed May 22, 1996. This number is the same as the application number listed on the oath/declaration and it is clear the oath/declaration is not defective.

Maintained Objection

Claim Objections

5. Claim 13 recites "Ig2a" which is not consistent with similar language previously presented. Claim 13 should recite "IgG2a".

6. Claim 16 continues to be objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants have amended claim 13 to indicate that the anti-idiotypic antibody must be [bound] to at least a Lewis Y carbohydrate expressing cell of a Lewis Y positive human breast cell line, see Remarks submitted July 16, 2004, bridging paragraph of pages 6 and 7. This amendment does not preclude the instant objection.

The independent claim 13 still reads on an anti-idiotypic antibody product that binds a breast cancer cell line (a narrow limitation) and dependent claim 16 reads broadly on cancer cells of epithelial origin. As such claim 16 reading broadly on all cancer cells of epithelial origin is not further limiting from the said independent claim. Applicants are reminded that this objection requires cancellation of the claim(s), amending the claim(s) to place the claim(s) in proper dependent form, or rewriting the claim(s) in independent form.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 13 is vague and indefinite in the recitation "...inhibition of binding of BR55-2 murine Ig2a to at least a Lewis Y carbohydrate expressing cell of a Lewis Y positive human breast cancer cell line...". This phrase is not clear. The phrase seems to recite that the Ig2a antibody is inhibited from binding a cell of a breast cancer cell. The phrase is nonsensical. Applicants are requested to clarify what is being claimed.

Maintained Rejections

Claim Rejections - 35 USC § 102

9. The rejection of claims 13-19, 23 and 28 under 35 U.S.C. 102(b) as being anticipated by Loibner et al. (Abstract from 7th International Congress of Immunology, Berlin, July 30-August 5, 1989/ IDS Reference, filed page 3, November 29, 2002 and February 24, 2003) is maintained.

Applicants arguments rely on a Declaration by Dr. Loibner submitted with a preliminary amendment filed February 18, 2003 in which Dr. Loibner attempts to differentiate between the antibodies of the claimed invention and the prior art. Also in hopes of obviating the instant rejection Applicants have amended claims 13 and 15, as well as present results of experiments in a Declaration by Dr. Gunter Waxenecker. These results "...indicate that not all of the isolated antibodies produced from several hybridoma cell lines are internal image antibodies that show more than 95% inhibition in terms of binding BR55-2 murine IgG2a to a Lewis Y positive human breast cancer cell line at a concentration of less than or equal to a ten fold excess of Ab2 to Ab1.", see Remarks, bridging paragraph of pages 7 and 8. These arguments, the declaration of Waxenecker and points of view have been carefully considered, but found unpersuasive.

Applicants' arguments, declaration, as well as the interview with Dr. Susan Gorman conducted on August 10, 2004 rely on the method used to produce the claimed anti-idiotypic antibody in order to differentiate between what is claimed and the prior art. Purportedly, the claimed antibodies are different from the antibodies of the prior art

reference because the art teaches production of a mixture of antibodies and does not show more than 95% inhibition in terms of binding BR55-2 murine IgG2a.

The Examiner reiterates that the Loibner reference discloses anti-idiotypic antibodies against BR55-2 useful for active tumor immunotherapy produced using a screening method selecting for anti-id properties, see title. The disclosed anti-BR55-2 antibodies bind the Y-tetrasaccharide antigen, which is expressed on the surface of human adenocarcinoma cells of breast, colon and lung. The Lewis Y (Le(y)) antigen is a difucosylated tetrasaccharide and accordingly these molecules are one in the same would bind the same binding moieties. These anti-idiotypic antibodies read on the claims. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Claim Rejections - 35 USC § 103

10. The rejection of claims 13-19, 23 and 28 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 4,971,792 (issued November 20, 1990)/ IDS Reference on sheet 1 of , filed November 29, 2002 and September 22, 2003) is maintained.

Applicants' aver "Potocnjak [does] not disclose or indicate a selection method for internal-image anti-idiotypic antibodies as described in the [instant] application".

Applicants arguments further attempt to differentiate between the prior art and what is claimed. Applicants again point to the Declaration by Dr. Waxenecker providing experimental evidence. These arguments and declaration have been fully reviewed and considered, but found unpersuasive.

It remains that U.S. Patent #4,971,792 teaches monoclonal antibodies BR55-2 (ATCC HB 9324), which bind to malignant cells expressing on or more determinants such as Y-6 and B-7-2. The patent does not teach monoclonal murine internal anti-idiotypic antibodies to the said monoclonal antibodies designated as BR55-2.

However, the patent '792 states "The isolation of other hybridomas secreting monoclonal antibodies with the specificity of the monoclonal antibodies of the invention can be accomplished by one of ordinary skill in the art by the technique of anti-idiotypic screening (Potocnjak, et al., *Science*, 215:1637, 1982).", see column 3, lines 10-40. Furthermore, the patent provides methods for ameliorating malignant disease in an animal using the taught monoclonal antibodies. And while Potocnjak does not describe the particulars of the screening criteria there is no evidence presented that would lead one of ordinary skill in the art to believe the anti-idiotypic antibodies utilizing the technique of Potocnjak would not act in the same manner as those claimed. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to produce anti-idiotypic antibodies specific for monoclonal antibodies BR55-2 and utilize in methods of cancer immunotherapy. Absent any evidence to the contrary the produced antibodies would act in the same manner as those claimed, i.e. retain equivalent inhibition capacity and produce immune response

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against Lewis Y carbohydrate-expressing cells. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the recited patent as well as the fact that anti-idiotypic responses are complementary to antibody responses since they both play roles in regulating humoral and cell-mediated immunity.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alana M. Harris, Ph.D.
20 September 2004


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

21 Sept 2004